Reducing Revenue Loss and Patient Financial Toxicity with a Pharmacy-Managed Pre-Certification and Denials Management Program

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In an era of soaring drug prices, payers have developed complex strategies to manage costs and ensure clinically appropriate prescribing in the outpatient environment.[1-3] Some of the most frequently used strategies include requiring prior authorization before treatment and implementing medical coverage policies with clinical criteria outlining coverage parameters. Because providers are unable to bill for a drug prior to dispensing it, institutions are often left balancing the need to start expensive treatments with uncertainty about reimbursement. A proactive approach to understanding and complying with payer-mandated requirements is vital to ensuring that millions of dollars in treatments are not lost to payer denials.

In 2018 CEOs responding to a national Advisory Board survey indicated that cost control is the number one priority for healthcare systems.[4] Whether through expense reduction or revenue growth, there is intense focus, now more than ever, on developing a sustained plan for margin protection.[4] Payer cost containment strategies not only help protect institutional margins, but they also impact patient care—clinically and financially.

In a 2018 American Medical Association survey of more than 1,000 physicians, 28 percent said that issues with the prior authorization process in their institutions have affected patient care delivery and led to serious adverse events, including death,

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hospitalization, disability/permanent bodily damage, and other life-threatening events.[5] This finding underscores the necessity of an efficient and effective institution-wide prior authorization process, with content experts dedicated to this work.

Adverse clinical outcomes are not the only casualty of poor cost containment policies; patient financial toxicity, especially in cancer care, is also a significant outcome.[6-10] Having high out-of-pocket treatment expenses can have the same consequences as compromised clinical care in that excess costs can decrease a patient's quality of life and hinder the delivery of care if a patient must decide between paying for treatment and funding other basic needs.

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Pharmacy Takes Center Stage

In 2009 the University of North Carolina (UNC) Medical Center significantly expanded its infusion services with the opening of the North Carolina Cancer Hospital in Chapel Hill. UNC also has cancer and infusion centers across the state to provide regional cancer care.

In 2016 an internal multidisciplinary quality improvement project examining Medicare infusion denials drew attention to the current process at UNC Medical Center for handling high-dollar infusion claims and denials. Until that time, the pharmacy department at UNC Medical Center handled pre-certification, and the hospital billing department at UNC Medical Center oversaw post-claim denial management, which is customary in most healthcare organizations.

Our pharmacy leadership believed that it would be more effective to transition our denials management process from hospital billing and into a closed-loop, collaborative system operated and managed by UNC Medical Center's Department of Pharmacy. The expanded pharmacy-managed pre-certification and denials management program that was subsequently created incorporates three discrete elements: a pre-certification program, a denials management program, and a continuous quality improvement program (see Figure 1, right). Six key steps were essential to creating and implementing the pre-certification program:

1. Developing an institutional pre-certification policy
2. Determining process owners
3. Building a streamlined process
4. Engaging pharmacy operational areas
5. Optimizing manufacturer-supported patient assistance programs
6. Developing a proactive medical necessity policy review.

After first transitioning denials management from hospital billing to the pharmacy department, we launched our pharmacy-led denials management program by hiring a pharmacist dedicated to working Medicare infusion denials. Shortly afterward, the pharmacist also assumed responsibility for denials from commercial payers and Medicare Advantage plans. We then added a denials specialist to the team to handle the expanding workload.

This pharmacist/denials specialist team is currently responsible for appealing denied drug claims and working with payers to resolve billing and claim processing issues that have resulted in these denials. The team assesses each denial, documents root causes, and tracks each one through to its final determination. Vital to the denial management program's success is the role that operational pharmacists play in ensuring adherence to the institutional policy for verifying that pre-certification referrals are authorized prior to dispensing. To support this effort the denials management pharmacist holds monthly meetings with operational leaders to share area-specific denial data. This includes information about drug- and payer-specific details as well as the root causes of individual denials. These meetings enable area leaders to stay aware of key drug and payer coverage trends and to collaborate in developing and implementing proactive multidisciplinary workflow changes.

This closed-loop collaboration model also enables continuous quality improvement among the pre-certification and denials management teams. In weekly meetings, representatives from both teams discuss the payer trends they observe during pre-certification and in denials data. This forum gives participants the opportunity to collaborate in developing, optimizing, and assessing front-line processes.

New Processes for a New Approach

As part of transitioning the responsibility for pre-certification to the pharmacy department, our organization implemented a mandatory medical benefit pre-certification program in our outpatient settings. Central to this program are the requirements that:

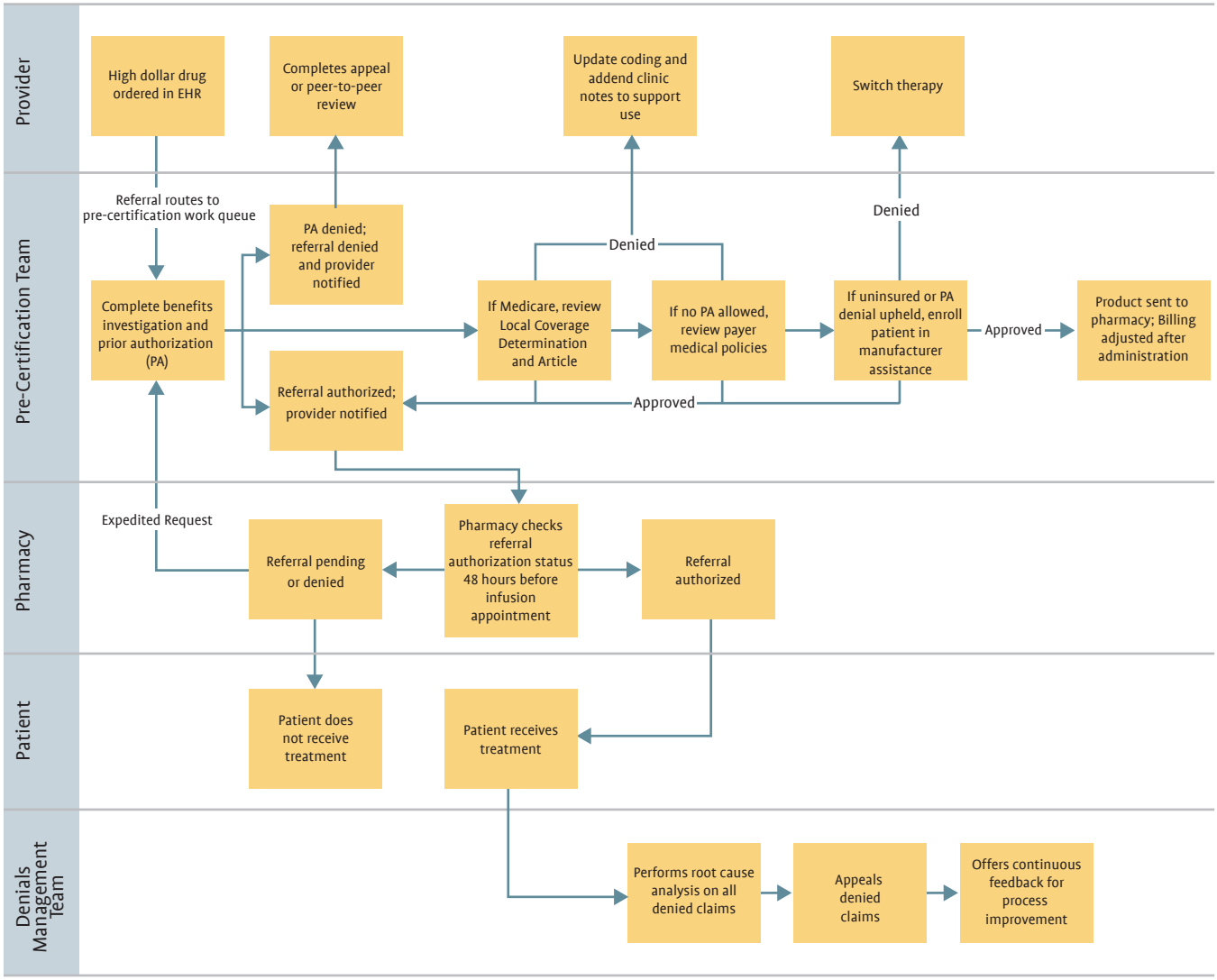
1. Outpatient medical benefit orders (e.g., infusion drugs) be entered seven days prior to treatment to allow time for pre-certification
2. Drugs are not dispensed until pre-certification is obtained.

Implementing these requirements was challenging. It required the support of senior leadership and physician administration to send the message that, in addition to protecting revenue, this policy would mitigate the risk that treatments would go uncovered and potentially leave patients responsible for their medical costs.

At the time, the UNC Medical Center pharmacy department's Medication Assistance Program team—staffed by advanced pharmacy technicians—was already overseeing prescription benefit prior authorizations, co-pay assistance for select specialty drug therapies, and the pharmacy's internal charity care program. It was logical to add responsibility for medical benefit pre-certification to this group, because team members were already familiar with the processes this task required.

Because we were launching a new electronic health record (EHR) when we created the medical pre-certification program, our pharmacy administration collaborated with leadership from

Figure 1. Standardized Workflow Process for Medical Benefit Pre-Certification and Denials Management Program



our information technology department to develop a referral process for outpatient infusion drug orders. The information technology team built into the EHR a referral order that is automatically sent to the pre-certification team whenever an order for a high-dollar infusion drug is generated.

These referrals are routed to a work queue managed by the pre-certification team. Once technicians receive a referral, they complete a benefits investigation to determine the patient's expected insurance coverage and out-of-pocket responsibility. If the payer requires a prior authorization, the technician will retrieve pertinent clinical information about the patient from the EHR and/or contact the prescriber for additional information. The technician will then submit the prior authorization request and track it through to completion.

All documentation is completed within the EHR and is transparent to all members of the healthcare team. Once an order is approved, the referral status is marked as authorized, which indicates to the operational pharmacy staff that a patient has been approved for treatment. The system sends an electronic message to the ordering provider communicating the approval. If a prior authorization request is denied, the technician works with the provider to appeal the decision.

The Last Line of Defense

Engaging the pharmacy operational areas is key to ensuring that high-dollar drug doses are not dispensed prior to authorization by the pre-certification team. This is the last line of defense in confirming that the dose is expected to be covered by the payer prior to it being administered to the patient. To accomplish this, the operational area team (pharmacists in the compounding area, preparing and dispensing drug product) reviews the outpatient infusion center schedule at least 48 hours before the scheduled treatment date. If the scheduled therapy is not authorized by then, the operational area team communicates with the pre-certification technician to rush the authorization, if possible, and/or communicates with the clinical and scheduling teams to have the patient's infusion appointment re-scheduled.

The automatic referral infrastructure developed for pre-certification also serves as a platform for identifying patients who qualify for manufacturer patient assistance programs. Following pre-certification, if a patient is identified as uninsured, or if his or her treatment is not covered by insurance, the pre-certification technician partners with the patient and provider to apply to the manufacturer for assistance. If the application is approved, the technician is responsible for ordering the product prior to each treatment date and coordinating billing adjustment. This enrollment is vital to certify drug access at no cost to the patient.

In 2018 our institution recognized the need to embed additional proactive reviews into our pre-certification process. The need for this was evident when our denial data increasingly indicated that payers that do not require prior authorization will still deny claims based on their published medical policies. In response to this growing trend, we implemented an additional step for referrals that did not require prior authorization in which a pharmacist reviews medical policies and assesses clinical documentation to confirm alignment. If permitted by the payer, the technician may request a pre-determination, essentially a proactive review of medical records by the payer.

New Collaborations

Key to the continuous quality improvement strategy of this effort is the development of collaborative relationships among the various health system teams central to the pre-certification and denials process.

The transfer of denials management from the hospital billing, revenue cycle, and patient financial services team at UNC Medical Center to the pharmacy-led denials management team created an organic partnership between these groups. Pharmacy's active engagement in denials management has also led to its close collaboration with the health system denials management team. Initially created in response to specific quality improvement concerns, this relationship has grown with pharmacy's expanding

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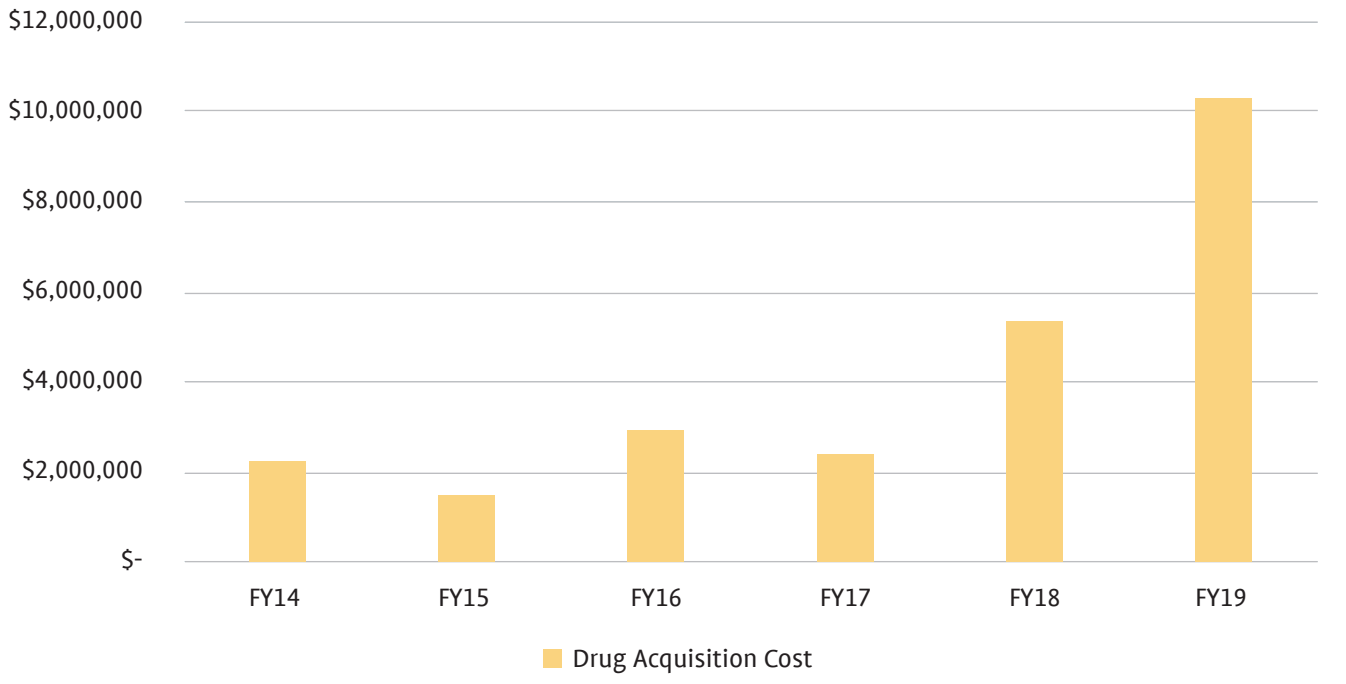
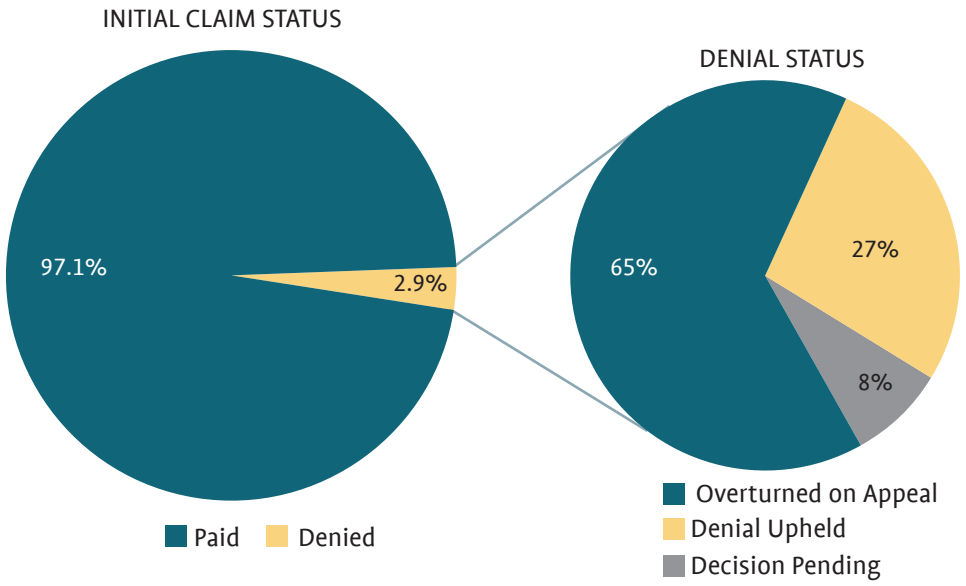
Figure 2. Drug Expense Savings Through Manufacturer Patient Assistance Program Enrollment*



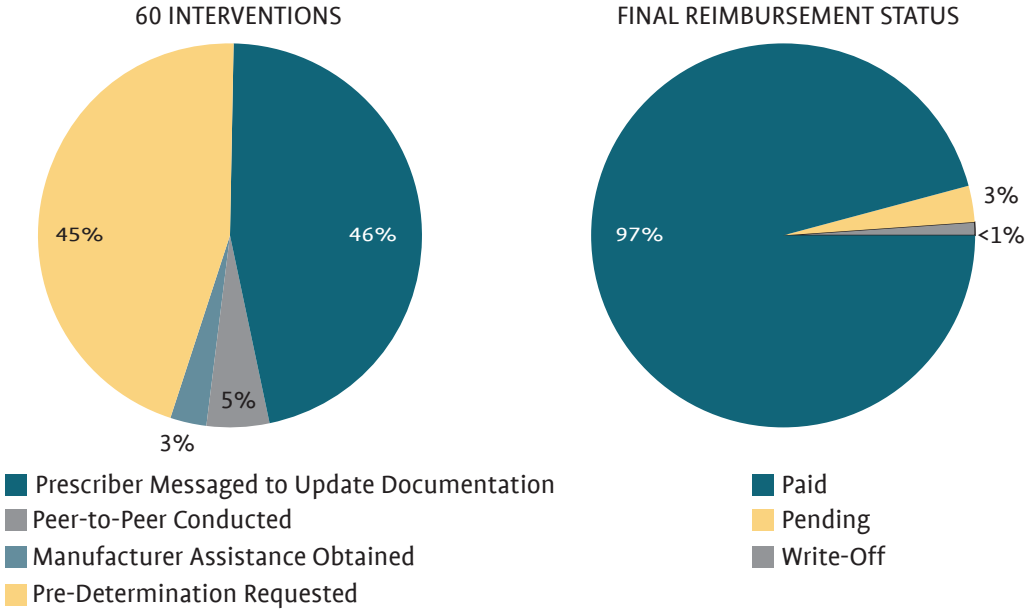
*These data represent manufacturer-provided medications offsetting drug expense to the institution and on behalf of patients. Drug acquisition cost is based on 340b drug price to UNC Medical Center.

Figure 3. Denials Management Program Financial Impact (July 2018-June 2019)



Reimbursement received to date	~$5.3M

Figure 4. Medical Necessity Proactive Review Financial Impact (September 2018-February 2019)



Reimbursement received*	~$2.2M
Write Off Amount	$2,706

*Reimbursement = Doses given within 6 weeks of initial dose

(continued from page 34)
efforts to decrease the denial rate, mitigate institutional revenue loss, decrease patient financial toxicity, assess current processes, and foster front-end change.

The pre-certification and denials management team has also developed a working relationship with the health system managed care team at UNC Health with which it has worked to handle new issues arising from the market introduction of high-dollar, niche drugs and from new trends in payer denials and reimbursement. Because accurate claim coding is also essential to avoiding denials, the pharmacy team works routinely with representatives from the health information management and coding team to ensure streamlined, accurate coding of high-dollar infusion claims.

A Wise Investment

As of October 2019, our pre-certification program has grown from a four-member team to 13 employees, including:

- Seven certified pharmacy technicians who complete more than 11,000 pre-certifications per year, the majority within 72 hours of when the drug is ordered
- Four certified technicians dedicated to enrolling patients into manufacturer assistance programs
- One medical necessity specialist
- One technician supervisor.

When patients are uninsured or when drugs are prescribed for off-label use, the pre-certification and post-treatment denials management processes include enrolling patients into manufacturer-supported patient assistance programs. Program enrollment in these programs in fiscal year 2019 resulted in $10.2M in annual drug cost savings to our institution based on drug acquisition cost. Figure 2, page 34, highlights the $24.8M total drug cost savings we have achieved since program creation.

With our streamlined denials management program with clinical pharmacist oversight, more than 65 percent of denied claims are overturned upon clinical appeal or payer reprocessing, resulting in more than $5.3M in actual reimbursement annually (see Figure 3, page 35). The combined work of the pre-certification and denials management teams also minimizes institutional revenue loss to less than 0.75 percent of the annual outpatient infusion revenue stream.

Our proactive, pre-claim medical necessity reviews affect treatments responsible for more than $4M in annual institutional drug reimbursement. Figure 4, page 35, highlights the number of drug orders evaluated for medical necessity from September 2018 to February 2019. Of the 232 drug orders, 60 required interventions, including asking the provider for additional documentation, requesting pre-determination, organizing peer-to-peer calls between the prescriber and payer representative, and enrolling the patient in manufacturer assistance programs. To date, treatments undergoing proactive medical necessity review have resulted in only one case of post-treatment drug revenue loss.

The UNC Medical Center pharmacy-managed, closed-loop medical benefit pre-certification and denials management program represents an innovative and unique approach to mitigating the patient financial toxicity and institutional revenue risk associated with payer cost containment strategies for high-dollar outpatient administered drugs. The institutional financial stewardship and patient financial savings since program implementation demonstrate a best practice that can be replicated at other institutions. OI

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